REMARKS

This paper responds to the Final Office Action sent on July 26, 2010.

Applicants note that the U.S. Specification as filed (U.S.S.N. 10/572,502, filed March 17, 2006) and the Substitute Specification filed the same day via a Preliminary Amendment have different line and paragraph numbering schemes. To avoid confusion, Applicants will refer to the relevant paragraph numbers in this application's corresponding U.S. Patent Application Publication 2007/0071816 (published March 19, 2007; hereafter U.S. Pub. '816). Applicants will refer to the "Red Line" Preliminary Amendment filed with the application on March 17, 2006, when necessary.

Status

Replacement Figures 1-5 are submitted to correct an inadvertent labeling error in Figure 1B and to reorient Figure 2B.

Claims 25, 28, 29, 30, 31, 38, 39, and 42 are amended; claims 32 and 33 are cancelled without prejudice or disclaimer; and no claims are added. Claims 1-24 and 41 were previously cancelled without prejudice or disclaimer. As a result, claims 25-31, 34-40, and 42 are now pending in this application.

Claim 25 is amended to recite that the core comprises one or more active ingredient composition regions and a separate swellable or reactive composition region, the one or more active ingredient composition regions comprising at least one pharmaceutically active ingredient and one or more pharmaceutically acceptable excipients, wherein in at least one active ingredient composition region, atleast one pharmaceutically acceptable excipient is a rate controlling excipient. Support for a separate swellable or reactive composition region is found at least in figures 1B, 1C, 2B, and 2C; at paragraphs [0088], [0097], [0101]-[0104], and [0105]; and the examples described at paragraphs [0109], [0115], [0120], and [0123]. Support for the term "rate controlling excipient" is found at least at paragraphs [0099], [0100], and the examples described at paragraphs [0109], [0115], [0120], and [0123].

Claims 25 and 42 are further amended to recite that "the swellable or the reactive composition region is located in an immediate vicinity of one or more preselected portions of the coating." Support for this amendment is found at least at paragraphs [0001], [0014], [0075], and [0082] of U.S. Pub. '816.

Claims 25 and 42 are also amended to recite the presence of a water-insoluble polymer coating surrounding the core. Support for the term "water-insoluble coating" is found at least at paragraphs [0083] and [0096] of U.S. Pub. '816.

Claims 25 and 42 have also been amended to correct typographical and grammatical errors. Numerals and indentations have also been provided for the various paragraphs for the convenience of the Examiner.

Claims 28 and 29 have been amended to change their dependencies.

The amendments to claims 30 and 31 are fully discussed below.

Claims 32 and 33 are cancelled. The subject matter of claims 32 and 33 has been incorporated into claim 25.

Claim 38 is amended to delete the term "composition" and recite that the active ingredient is released without substantial delay.

Claim 39 is amended to recite an outer coating including a pH-dependent polymer. Support for this amendment is found at least at paragraphs [0059] and [0070] of U.S. Pub. '816.

Claim 42 is amended in a manner similar to claim 25.

No new matter has been added with these replacement figures and claim amendments.

Replacement Figures

Replacement Figures 1-5 are submitted to correct an inadvertent drawing error. In Figure 1B the placement of layers 4 and 5 was reversed. Replacement Figure 1B now correctly indicates that the swellable composition (5) is located in communication with a preselected portion of the coating (i.e., the passageway (3)). Support for replacement Figure 1B is found at least at page 11, paragraph [18] of the "Red Line Specification" of the Preliminary Amendment filed with the application on March 17, 2006.

Figure 2B has also been redrawn merely to reorient it in a manner similar that shown for Figures 1B, 1C, and 2C.

Summary of the Rejections

I. Claims 31 and 42 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

II. Claims 25-32, 34-38 and 42 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hayashida et al. (U.S. Patent No. 5,593,694; hereafter '694).

III. Claims 25, 26, 28, 30-40 and 42 were rejected under 35 U.S.C. § 102(b) as being anticipated by Conte et al. (U.S. Patent No. 6,294,200; hereafter '200).

Each of these rejections will be dealt with in turn.

Rejection Claims under 35 U.S.C. § 112

I Claims 31 and 42 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Ia. The Office Action asserts that "Claim 31 recites that the 'active ingredient present in the one or more layers is different', however if the drug delivery system comprises one layer, what is the active ingredient different from? It is unclear what exactly is being claimed, whether the active ingredient is different from the other components of the core (an inherent feature) or if other, separate layers are required that differ in some way from one another. If the latter is the case, the term 'different' would be relative as there is no definition of limit to differences in composition down to the molecular level, i.e. multiple levels could have HPMC and naproxen, where one layer have HPMC of a higher molecular weight than the other, or of a different granular size, etc. Clarification of this claim is required." For the purposes of Examination, the

Office Action interpreted the invention recited in claim 31 as a drug delivery system where the active ingredient and swellable composition are present in one layer.

Claim 31 has been amended and now recites that "wherein the active ingredient in any one of the active ingredient composition layers may be the same or different from the active ingredient in any of the other active ingredient composition layers." Support for this amendment is found at least at paragraphs [0101] to [0104] of U.S. Pub. '816.

> [0101] "In one embodiment of the present invention, the core comprises—
> [0102] a. a first layer of active ingredient composition
> [0103] b. a second layer of active ingredient composition, and
> [0104] c. a third layer of a swellable composition,
> wherein the active ingredient compositions of the first and second layer may comprise active ingredients that are same or different, and the swellable composition comprises a swelling agent, and may or may not comprise an active ingredient"

The amendment to claim 31 necessitated amending claim 30 to recite that the "the one or more active ingredient composition regions are is in the form of one or more layers and the swellable composition region is in the form of one or more layers." Support for this amendment is found at least paragraphs [0037] and [0038], Figures 1B, 1C, 2B, and 2C of U.S. Pub. '816, and in the Preliminary Amendment filed on March 17, 2006.

In view of the above amendment and remarks, Applicants respectfully request withdrawal of this rejection of claim 31 under 35 U.S.C. § 112, second paragraph.

Ib. The Office Action asserts that, "Claim 42 recites an orally administrable drug delivery system in the form of a multilayered tablet, yet only recites one layer. The core comprises at least one layer comprising an active ingredient composition and a swellable or reactive composition. No other layers are recited. As such the claim reads on any monolithic tablet with a coating surrounding it, and not on a multilayered tablet." For the purposes of Examination, the Office Action interpreted the invention as recited in claim 42 as a single layer tablet with a coating surrounding it.

Claim 42 has been amended as recited above. Support for the amendments is found at least at paragraphs [0037] and [0038], in Figures 1B, 1C, 2B, and 2C of U.S. Pub. '816, and in the Preliminary Amendment filed on March 17, 2006. The term "consisting of" is supported at least at paragraphs [0116], [0117], [0118], and [0120] of U.S. Pub. '816, wherein the first layer consists of an active pharmaceutical ingredient composition and the second layer consists of a swellable composition.

In view of the above amendment and remarks, Applicants respectfully request withdrawal of this rejection of claim 42 under 35 U.S.C. § 112, second paragraph.

Rejection Claims under 35 U.S.C. § 102

The rule under 35 U.S.C. §102 is well settled, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP §2131. "[F]or anticipation under 35 U.S.C. §102, the reference must teach *every aspect* of the claimed invention either explicitly or impliedly." MPEP §706.02 (emphasis added).

Applicants respectfully submit that amended independent claims 25 and 42 are not anticipated by Hayashida et al. ('694) or by Conte et al. ('200), because neither document teaches each and every aspect of the presently claimed invention.

II. Claims 25-32, 34-38 and 42 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hayashida et al. (U.S. Patent No. 5,593,694; hereafter '694).

The Office Action asserts that, "The '694 patent teaches an oral administrable drug delivery system comprising a core and a coating (abstract). The core comprises an active ingredient along with an excipient (col. 5, lin. 60-col. 6, lin. 65). The core tablet further comprises swellable portions (col. 4, lin. 34-60). The core is surrounded by a coating that is in immediate vicinity of the drug and swellable portions. The periphery of the coated tablet is thinner than the top and bottom and upon administration will absorb water (col. 4, lin. 12-34). The coating is semipermeable to water around the edges (col. 7, lin. 10-20). The water

absorption activates the water swellable portions of the core tablet forcing release of the active agent, while the top and bottom portions of the coating remain intact (Figures 2A, 2B). The sides of the coating are preselected to be removed after contact with the aqueous environment of the body, while the top and bottom portions are not removed ***(Ibid.)*** Since the tops and bottom of the dosage form does not dissolve or transmit drug to the aqueous environment, the side act as passageways for the drug to move through. The swellable agents include cellulose wicking agents, and osmogents such as lactose (col. 5, lin. 60-65). The dosage form is capable of zero-order release of the active agents (col. 7, lin. 30-35). The solid core tablet is a compressed tablet comprising a single layer of the components comprising both the active ingredient components and the swellable composition (Examples). These disclosures render the claims anticipated."

Claim 32 has been cancelled; therefore the rejection to claim 32 is moot. In so far as this rejection pertains to independent claims 25 and 42, and dependent claims 26-31 and 34-38, Applicants respectfully traverse this rejection.

Claims 25 and 42 have been amended as recited above. Support for these amendments is found at least at paragraphs [0037] and [0038] and Figures 1B, 1C, 2B, and 2C of U.S. Pub. '816 and in the "Red Line" Preliminary Amendment filed on March 17, 2006. Support for the term "consisting of" is found at least at paragraphs [0116] and [0118] of U.S. Pub. '816, wherein the first layer consists of an active pharmaceutical ingredient composition and the second layer consists of a swellable or reactive composition.

Claims 25 and 42 have also been amended to recite the presence of "at least one pharmaceutically acceptable excipient that is a rate controlling excipient" in the active ingredient composition region or layer respectively. Support for this amendment is found at least at paragraphs [0099], and [0100] and the examples described at paragraphs [0109], [0115], [0120], and [0123] of U.S. Pub. '816. As presently claimed, the active ingredient provides control over the release of the active ingredients because of the presence of rate controlling excipients. The swellable or reactive composition is designed such that, upon contact with aqueous environment, the material of the swellable or reactive composition does not hinder the release of its contents.

This is because the swellable or reactive composition is substantially free of rate controlling excipients.

In contrast to Applicants' claimed combination, the sustained release tablet of the '694 patent teaches "a sustained release tablet comprising a single region base tablet containing a water-swellable gelling agent and a pharmaceutically active ingredient dispersed homogeneously in said gelling agent, said single region base tablet being coated with a film coating composition prepared by dissolving one or two members from ethylcellulose and acetylcellulose in an organic solvent. (*See,* column 3, lines 26-32; emphasis added).

Applicants' oral drug delivery system is novel over that described in the '694 patent because of Applicants' unique construction of a core having separate regions. Applicants wish to point out that the '694 patent fails to disclose or suggest two distinct separate regions of the active ingredient composition and the swellable or reactive composition region as presently claimed. Applicants' claimed distinct separate regions allows a pre-selection of the one or more portions of the surface from where the coating is removed partially or fully, when the system comes in contact with an aqueous environment. Thus, there is one or more definite preselected surfaces from where the coating gets removed. The coating in the vicinity of the active ingredient composition region, which is the remaining portion of the coating, is not removed.

Thus, the '694 patent, fails to not only disclose but even provide a slightest suggestion of the effect of removal of the coating from a preselected surface. This effect is achieved because of the core having separate regions having an active ingredient composition and a swellable or reactive composition.

Applicants' oral drug delivery system therefore contains at least two separate regions in the core compared to the prior art '694 patent that does not contain two separate regions in the core. Therefore, the prior art does not anticipate the claims in the present oral drug delivery system. For the same reasons, Applicants' believe that the prior art '694 patent does not render the claims in Applicants' oral drug delivery system obvious.

Because each and every element of the claims is not disclosed in the '694 patent, claims 25-31, 34-38, 40, and 42 cannot be anticipated, and are novel over the cited prior art.

In view of the forgoing amendments and remarks, Applicants respectfully request withdrawal of the rejection and allowance of claims 25 and 42. In as much as claims 26-31, 34-38, and 40 depend either directly or indirectly from claim 25, Applicants respectfully request withdrawal of the rejection and allowance of these claims as well.

III. Claims 25, 26, 28, 30-40 and 42 were rejected under 35 U.S.C. § 102(b) as being anticipated by Conte et al. (USPN 6,294,200; hereafter '200).

The Office Action asserts that, "The '200 patent teaches a coated tablet comprising a core and a coating (abstract). The core comprises layers (Figures), comprising an active pharmaceutical component comprising excipients (col. 4, lin. 55-65; col. 7, lin. 53-col. 8, lin. 26) and a swelling components (col. 5, lin. 29-40). The swellable components comprise swellable components like cellulose wicking agents, osmogents like lactose, (col. 5, lin. 10-25). The formulation comprises a second active ingredient that is released in an immediate release form (part 5, col. 3, lin. 60-65). The coating surrounds the core layers with the swellable layer in contact with the coating (part 2, Figure 3). The swellable components are present as an in-lay tablet layer surrounded by the coating (Figures). Upon release the immediate release portion is removed and exposes the core layers. The coating polymer is impermeable to the drug composition comprising cellulose phthalates (col. 6, lin. 25-45). The formulation is further coated with a pH dependent coating (col. 7, lin. 10-20). These disclosures render the claims anticipated."

Claims 32 and 33 have been cancelled; therefore the rejection to claims 32 and 33 is moot. In so far as this rejection pertains to independent claims 25 and 42, and dependent claims 26, 28, 30-31 and 34-40, Applicants respectfully traverse this rejection

Claims 25 and 42 have been amended and presently recite that Applicants' orally administerable drug delivery system comprises "a water-insoluble polymer coating surrounding the core." Support for these amendments is found at least at paragraph [0083] and paragraph [0096] and in Figures 1 and 2 of U.S. Pub. '816.

In contrast to Applicants' claimed combination, Figures 3 and 4 of the '200 patent teach a layered core having two different coatings (part **4** and part **5**), each partially covering a portion of the core, each having a different function and a different composition. Part **4** is a water impermeable coating that partially covers a portion the core on the lower and lateral surfaces. (*See*, column 3, lines 47-48). Part **5** is a soluble coating that "is characterized by having a composition able to allow for the fast release of the active substance itself." (*See,* column 3, lines 62-65). This distinction is further elaborated upon, "This core is coated by compression, on the upper part by a fast disintegration and dissolution coating **5** containing an active substance quantity which is quickly released and on the lateral surface of layer **2** whereas on the lateral and lower surface of layer **3** by the coating **4** which forms a barrier impermeable for a specified period of time." (*See*, column 4, lines 33-37; emphasis added.)

Thus, in the '200 patent, the water impermeable coating **4** only partially covers the core and does not surround the core with the same coating material, as presently recited in claims 25 and 42. In contrast, Applicants' presently claimed combination recites that a water-insoluble polymer coating (Applicants' part **2**) completely "surrounds" the core.

Because each and every element of the claims is not disclosed in the '200 patent, claims 25-31, 34-40, and 42 cannot be anticipated, and are novel over the cited prior art. For the same reasons, Applicants' believe that the prior art '200 patent does not render the claims in Applicants' oral drug delivery system obvious.

In view of the forgoing amendments and remarks, Applicants respectfully request withdrawal of the rejection and allowance of claims 25 and 42. In as much as claims 26, 28, 30-31, and 34-40 depend either directly or indirectly from claim 25, Applicants respectfully request withdrawal of the rejection and allowance of these claims as well.

CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' representative at (612) 373-6961 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402--0938
(612) 373-6961

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By /Louis M. Leichter/
Louis M. Leichter, Ph.D., J.D.
Reg. No. 34,657

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 29 day of Sept. 2010.

John D. Gustav-Wrathall
Name

/John D. Gustav-Wrathall/
Signature